

March 23, 1999

Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

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Dear Sirs,

I hope this letter is not too late - I just found out today about the plan to limit specialized pharmacies regarding shipping compounded prescription medications for personal use across state lines. I am very upset to hear this.

I am unable to take synthetic forms of **progestins**. I initially tried a local pharmacy which is supposed to be very good at compounding medications. However, **when they compounded the progesterone my physician ordered**, I had a lot of problems with it. **After** speaking with the pharmacists at Madison Pharmacy, I found out **the** problem was due to what they were using as a base with the progesterone, and they were unwilling to change how they did it (not because of medical reasons, but because they weren't willing/able to change at this point). They are **good** pharmacists, and I still get some compounded medications from them. But their expertise is **not** in hormones for women.

I chose to order my prescription hormone medications compounded at Madison Pharmacy Associates in Wisconsin because of their years of expertise in working with these medications. As a Women's Health Nurse Practitioner, I did a lot of research before deciding to use Madison Pharmacy in Wisconsin.

The pharmacists at Madison Pharmacy have been very knowledgeable and helpful in guiding my physician and me, as we have tried different formulations and doses until we found what works best for me. One "size" of medication does not fit everyone. I pay the cost of shipping my medication because it is worth it **to** me to know I am getting the medication that has been ordered for me, and the pharmacists know what they are doing.

How can the FDA presume to take away my right to chose where I get my medications? Women are tired of having their **health** care choices legislated by government. I can order standard pharmaceutical medications from a pharmacy out of state through my Health Insurance plan - in fact, they encourage members to do this. But that pharmacy only provides medications made by the pharmaceutical companies. The hormonal preparations available for women, especially those needed for PMS, **peri-menopause**, and menopause syptoms are quite limited from these companies. They only provide certain doses of synthetic hormones. For some women these work fine, but **for many other women they** often have such **severe** side effects that patients don't ever **fill** the prescriptions, or **simply** stop taking them. There are ample studies that show this to be true.

Please do not take away any more of women's choices, which this legislation would do. Pharmaceutical companies will never provide these medications because it would not be profitable **for** them. If your concern is the quality assurance of the medications compounded - being sure that what the pharmacy says is in the medication provided is really there - this is not the way to accomplish this.

Sincerely,

Kimberly O. Miner

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10PPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular,
10BJECT to the definition of "inordinate amount" which restricts the availability
and the right to obtain medically necessary compounded medications by limiting
the number of prescriptions that can be shipped across state lines from specialized
compounding pharmacies.

Kimberly A. Minner
Signature

3/23/99
Date

COMMENTS: See attached letter

Please fold, seal, and mail by March 22

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